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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/481,572	01/11/2000	JACQUELINE J. SHAN	P8061-9013	5800
6449	7590	05/18/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			MELLER, MICHAEL V	
		ART UNIT	PAPER NUMBER	
		1654		

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/481,572	SHAN ET AL.
Examiner	Art Unit	
Michael V. Meller	1654	

**1. The MAILING DATE of this communication appears on the cover sheet with the correspondence address -- Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 25 February 2004 and 30 January 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,8,10,23,26 and 28-44 is/are pending in the application.
  - 4a) Of the above claim(s) 28-44 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 8, 10, 23, 26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Election/Restrictions***

Newly submitted claims 28-44 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims restrict the type of disease being treated wherein before the amendment the disease was only restricted to chronic heart failure, and to two new methods which are very different materially and in purpose and steps to the originally elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102***

Claims 1, 8, 10, 23, are rejected under 35 U.S.C. 102 (e) as being anticipated by Khwaja et al.

Khwaja teaches the use of St. John's Wort (*Hypericum perforatum*) extract to treat the claimed disease, see abstract, cols. 10, 20, 23-24, 27-28, etc. Khwaja teaches that such diseases/conditions (cardiac arrhythmia, angina, diabetes, hypertension) can be treated with the extract.

Applicant argues that Khwaja teaches a number of assays that can be used for testing for substances for consistent quality and suitability as a therapeutic agent, but it is clear on col. 27, lines 35-end through col. 28, line 35 that these materials taught by the patent are useful for the above mentioned disease states which are claimed by applicant.

### ***Claim Rejections - 35 USC § 103***

Claims 1, 8, 10, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khwaja et al.

The above discussion is applied here. The arguments are the same as above. Thus, the rebuttal is the same as above.

Claims 1, 8, 10, 23, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khwaja et al. taken with Kikuta et al. '485 or Kikuta et al. '957.

The above discussion is applied here. The arguments are the same as above. Thus, the rebuttal is the same as above.

The Kikuta references each teach that *hypericum* is known to be used to treat congestive heart failure (which is also claimed by applicant in claim 1). Thus it would have been within the purview of the skilled artisan to administer the extract to someone having chronic heart failure since the primary references each teach using the extract for conditions such as cardiac arrhythmia, cardiac inotropy, and the Kikuta references teach using the extract to treat congestive heart failure. Since such conditions are closely related (as noted by the claims themselves) it would have been well within the purview of the skilled artisan to use the extract for the claimed purpose.

Applicant argues that there was a long felt need in the art but provides no real data to support this alleged fact. Fact is, the references make it clear that the extract was known for the purposes as argued above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael V. Meller  
Primary Examiner  
Art Unit 1654

MVM